Serial No.: 10/024,858
Group Art Unit No.: 1615

REMARKS

Applicants wish to thank Supervisory Examiner Thurman K. Page and Examiner Humera N. Sheikh for the courtesy extended Mr. Charles E. Van Horn esq. (co-counsel) and the undersigned attorney during the interview which took place on Wednesday, June 2, 2004.

During the interview applicants' representatives provided arguments that the prior art did not teach a composition containing paroxetine in a controlled and delayed release formulation, as claimed in the instant application. Applicants' representatives pointed out that nothing in the cited art taught or suggested applicants' new composition containing paroxetine in a controlled and delayed release formulation, or the method of treatment of claim 26.

Further, applicants' representatives provided arguments that it would not require undue experimentation to practice the invention. The cited reference to Johnson (WO 92/09281) indicated that delayed or controlled formulations were known but did not indicate that paroxetine could be or should be formulated in a controlled and delayed release formulation. Applicants' representatives noted that the specification contained definitions for the terms used in this application and multiple examples of compositions wherein paroxetine was formulated in a controlled and delayed release formulation. Specifically, example 12 and the disclosure in the specification on page 2, line 22 to page 3, line 26 were mentioned. The disclosure in the specification on page 2, line 22 to page 3, line 26 describe formulations that are now claimed in United States Patent No. 6,548,084, the parent of the subject application. Applicants' representatives also noted that paroxetine has been indicated in the treatment of the disease states of claim 26, as indicated by claims 1 and 4 of United States Patent No. 6,133,289. In view of the description in the specification and the examples when viewed from the perspective of the person skilled in the art, the present specification is considered to enable the practice of the invention without undue experimentation.

Applicants clearly showed the rejections were not sound.

Applicant's arguments were favorably considered and, as indicated in the interview summary, the rejections under 35 U.S.C. §112, first paragraph and 35 U.S.C. § 102(b) over Johnson (WO 92/09281) will be withdrawn.

Also discussed during the interview was the possibility of an issue of double patenting over US Patent No. 6,548,084, the parent of the instant application. A

decision was made to file a terminal disclaimer, enclosed herewith, in order to avoid the issue. In filing the terminal disclaimer, applicants' actions should not be construed as an admission that there is an issue of double patenting with respect to US Patent No. 6,548,084. Quad Environmental Tech. v. Union Sanitary Dist., 20 USPQ2d 1392.

Finally, upon the suggestion of the Examiners, the last line of claim 26 has been amended by changing "a sufferer" to ---an individual---. Support for this amendment is found on page 13, line 15 of the specification. An individual with one of the recited disease states may not be suffering, but would benefit from the administration of a formulation of claim 25. Accordingly, the claim has not been narrowed by this amendment.

Applicants therefore submit that all reasons for rejection have been addressed and that the claims, as amended, are allowable. Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned attorney at the number indicated below.

Respectfully submitted,

Wayne J. Dustman
Attorney for Applicants
Registration No. 33,870

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Phone (610) 270-5023
Facsimile (610) 270-5090
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